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SUBJECT: USUNESCO: NEGOTIATIONS ON BIOETHICS DECLARATION

**1.** SUMMARY. The second and final session of the Intergovernmental Meeting of Experts met June 20-24 at UNESCO and reached consensus on a draft "Universal Declaration on Bioethics and Human Rights." The US was successful in adding to the draft Declaration a statement that one of the aims of the Declaration is ensuring respect for the life of human beings and in deflecting efforts to have the document include "right to health," "special responsibility of human beings for the protection of the environment," and various other social agendas as bioethical principles. The United States received appreciation for its proposal concerning the "social responsibility" article, and this was instrumental in helping the US successfully oppose objectionable provisions. The draft declaration will be sent forward to the UNESCO General Conference in October 2005 for consideration and likely adoption. The negotiations were challenging but were generally conducted with respect. However, the process was deficient in several respects, resulting, inter alia, in insufficient time for governments to review and comment on the final revised text and meeting report. END OF SUMMARY

#### BACKGROUND

**2.** The first session of the Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics was held April 4-6, 2005. It considered the Preliminary Draft Declaration prepared by the independent International Bioethics Committee (IBC). The April session demonstrated widespread dissatisfaction by member countries with the IBC draft, but no consensus on the major issues, including the scope of the Declaration. Following this meeting, an informal discussion was convened by Ambassador Pablo Sader (from Uruguay), Chairman of the Meeting. Sader attempted to find compromise on the basis of that discussion and other consultations.

#### RESPECT FOR HUMAN LIFE

**3.** The Second Session of the Intergovernmental Meeting was held at UNESCO headquarters, June 20-24, 2005. At that meeting, the U.S. was successful in adding to the article on Aims (Article 2(iii) of the draft Declaration) a provision on respect for the life of human beings. Any reference to respect for the life of human beings had been vigorously opposed by a number of states in the previous meeting. The draft Declaration now states that one of its aims is "to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings.." The Declaration recognizes human life (or respect for it) as a part of human rights and thus incorporates it into the various provisions of the Declaration in which the term "human rights" is used. The ability to obtain consensus for this provision was facilitated by inclusion at the urging of the U.S. of language in the preamble that the Declaration is to be understood consistent with domestic and international law (see paragraph 6).

#### SCOPE

**4.** The U.S. delegation was successful in limiting the explicit scope of the draft Declaration to medicine and the life sciences; the definition of bioethics in the IBC draft that had included the social sciences and relationship to the biosphere was deleted. In addition, the U.S. was successful in limiting the explicit application of the draft Declaration to States to guide them in the formulation of their legislation, policies, or other instruments in the field of bioethics, with a reference to its also providing guidance to decisions or practices of private actors. (However, some of the actual provisions appear to be relevant only to private actors.)

#### DOMESTIC LAW

**5.** The U.S. insisted on a provision (in the Preamble, and accepted with revisions in a similar provision in Article 27) that the draft Declaration is to be understood in a manner consistent with domestic and international law; some articles also contain a provision referring to domestic law. (The French delegation attempted to delete the preambular

provision at the last moment, even though, as the Chairman stated, the consensus that had been reached on other items was made possible by the understanding that the preamble would contain this provision.) The U.S. successfully opposed inclusion of an explicit savings clause, pursuant to our policy for negotiating declarations.

#### CONSENT

16. The meeting had difficulty drafting the provisions on informed consent (now Articles 6 and 7). A large informal working group presented language to the plenary meeting for discussion. The Chairman gavelled it as agreed to after only brief discussion. Several countries objected strongly to the approval without meaningful discussion. Canada in particular objected to the fact that there was only minimal discussion and expressed formal reservations on the articles. The U.S. supported the Canadian objection. Article 6 contains a new paragraph (c), which had not previously been tabled, providing that in addition to obtaining the consent of individuals for research, researchers "may" obtain the "additional agreement of the legal representatives of the group or community concerned." (Comment: It is uncertain whether this has the potential to create additional expense and delay for research without benefit for the patient. End Comment)

#### SOCIAL RESPONSIBILITY AND HEALTH

17. Brazil proposed an amendment to the already problematic Article 13 in the IBC Preliminary Draft (now Article 14 in the Draft Declaration). Its amendment received broad support in the meeting (particularly from Andean countries). Its amendment made promotion of health and social development a "duty" of governments. It also drew from the WHO Constitution and referred to the enjoyment of the highest attainable standard of health as one of the fundamental rights of every human being. The U.S. countered with language referring to health and social development "for their people" as a "central purpose" of governments and restored the language from the WHO constitution left out of the Brazilian amendment (highest attainable standard of health is a fundamental right "without distinction of race, religion, political belief, economic or social condition"). The U.S. language also deleted the reference to "reproductive health." The U.S. compromise was adopted, and the U.S. was thanked for its constructive contribution and its cooperation. This increased support for the U.S. position on other items of concern to the U.S.

#### ENVIRONMENT

18. The U.S. was successful in changing a provision that would have made it a principle of bioethics that any decision or practice should take due regard of its effect on all forms of life and that there was a "special responsibility" of human beings for the protection of the environment. The agreed language (Article 17) deletes the reference to "special responsibility" and says that "due regard" is to be given to the interconnection between humans and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to the respect for traditional knowledge and to the "role" of human beings in the protection of the environment. The U.S. was also successful in opposing addition (in Article 21) of references to "biopiracy" proposed by Brazil and supported by the Andean states.

#### PRECAUTIONARY PRINCIPLE

19. The Preliminary Draft contained a muddled and potentially troublesome version of the precautionary principle. The U.S. was successful in substituting for it a provision (Article 20) saying that "appropriate assessment and adequate management of risk" should be promoted.

#### DECLARATION NOT CONVENTION

10. The U.S. was successful in changing the tone and words of the Declaration in several ways to make it consistent with the fact it is a declaration, not a binding instrument: the word "shall" was replaced in each instance by "is (are) to be" or "should"; the concept of "implementation" was removed; the provision for reports to UNESCO by states was deleted; the roles envisaged for the IBC and IGBC (the Intergovernmental Bioethics Committee) were reduced considerably, and UNESCO was directed to promote cooperation between them; and the reference to future instruments was deleted.

#### PROCESS

11. UNESCO seemed to be focused more on having a product for the General Conference than on the quality of that product. The overall process for developing the Declaration was not satisfactory. The amount of de facto control given to the

IBC (a group of independent "experts") was particularly troublesome. The IBC was directed to prepare a recommended draft. It met 6 times over an 18-month period. Member states had only limited input through the IGBC, and the suggestions made by the IGBC were not reflected in the IBC's Preliminary Draft. The IBC asked for more time to develop a draft but was pressured into finalizing its draft. This was presented to Member States as a consensus draft when in fact there were major disagreements among the members of the IBC itself and there was no consensus among Member States. The IBC prided itself on expanding the notion of bioethics to include protection of the environment and social responsibility and its "independence" from governments. The resulting Preliminary Draft presented by the IBC was not acceptable to Member States. They were presented with an unacceptable text that they had to fix, and to do it in only two sessions of the intergovernmental meeting, in which 90 states participated.

12. In addition, pressure from the Secretariat to have the document ready for this fall's General Conference meant there was not time for full consideration and good drafting. And there was little opportunity for any reflection or consultation with capitals about the language being drafted. The draft Declaration in fact was adopted after midnight as the translators were leaving without a chance for full consideration; there was no debate on the consent article. In addition, there was no opportunity to read or consider the report accompanying the draft. It was an uphill battle against a draft prepared in secret, by a small, nonrepresentative, and supposedly expert group who had been given no guidance by the Member States. The process was essentially upside down.

#### COMMENT

13. The U.S. was successful in blunting some of the most troublesome aspects of the Preliminary Draft presented by the IBC and of amendments that member states sought to make in the Intergovernmental Meeting. It succeeded in obtaining a reference to respect for human life. The result was better than could have been expected, particularly considering the poor process. There will be more discussions about the terms of the Declaration, and we will monitor efforts to change it. At the same time we await reactions as to whether there are provisions that would prevent the U.S. from joining consensus. We also will be vigilant to any efforts to turn the Declaration into a Convention and make clear our opposition to any such effort.

OLIVER